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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/563,273	07/24/2006	Rolf Berge	966917.00013	6395

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EXAMINER	
OGUNBIYI, OLUWATOSIN A	
ART UNIT	PAPER NUMBER
1645	
MAIL DATE	DELIVERY MODE
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/563,273	BERGE ET AL.	
	Examiner	Art Unit	
	OLUWATOSIN OGUNBIYI	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *03 July 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *22-43* is/are pending in the application.

4a) Of the above claim(s) *24-43* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *22 and 23* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *04 January 2006* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *7/16/08*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claims 22-43 are pending in the application. Claims 22-23 are under examination.

Election/Restrictions

Applicant's election with traverse of Group I claims 22-25 in the reply filed on 7/3/08 is acknowledged. The traversal is on the ground(s) that the PCT Examiner found during international proceedings that claims 1-21 which substantially corresponds to the present claims fulfill the Unity of Invention under PCT Rule 13.2 and Johannessen et al WO 01/160974 was cited as an A reference which defines the general state of the art but it not considered of particular relevance and that the reference does not teach or suggest a method of treating or preventing a disease involving a step of administering a pharmaceutical or nutritional composition comprising a single cell protein material and that the subject matter of the instant pending claims are related so that a thorough search for the subject matter of one group of claims would necessarily encompass a search for the other groups of claims and that the PCT Examiner as already searched prior art with respect to claims 1-21 in the corresponding PCT application PCT/NO2004/000204.

This is not found persuasive because the technical feature as identified by the National Stage Patent Office (USPTO) linking the three listed groups of inventions is a pharmaceutical or nutritional composition comprising a single cell protein material (see definition in the instant specification on p. 9 as a material comprising single cell microorganisms such as fungi or yeast or bacteria). The technical feature of the invention of Group I is a method of treating or preventing a disease comprising administering pharmaceutical or nutritional composition

comprising a single cell protein material to an animal in need of such treatment. The technical feature of the invention of Group II is a cardio protective pharmaceutical composition or pharmaceutical or nutritional composition comprising a single cell protein material. The technical feature of Group III is a method of changing the fatty acyl profile and for improving the lipid homeostasis of an animal comprising administering a pharmaceutical or nutritional composition comprising a single cell protein material to an animal in need of such treatment. Clearly Group II does not recite a method. Group I and Group II have the different recited preambles and as pointed out by Applicants, the preamble is a statement of the intentional purpose for which the method must be performed. Thus, the technical feature that is common to the three groups and which links the inventions as a whole is a pharmaceutical or nutritional composition comprising a single cell protein material. As pointed out in the restriction requirement this shared technical feature is not special under PCT Rule 13.2 because it is disclosed by the Johannessen et al reference and therefore the Groups do not relate to a single general inventive concept under PCT Rule 13.1. This examining office i.e. the Patent Office performed a separate search on the claims for the instant restriction requirement and found that the Johanneseen et al reference anticipates the common technical feature linking the Groups of inventions according to PCT Rule 13.1 and 13.2 not withstanding any search made by or decisions made by the international searching authority (which was not the Patent Office) or the PCT Examiner. Also note that claims 1-21 of the international application set forth 'use' claims which do not set forth active positively recited method steps thus the claims would have lacked clarity if the Patent Office were the searching authority. In addition to the above, the technical feature of Group I drawn to the first mentioned invention in the claims is also anticipated by the

art. Pang et al (WO 02/34273 A1 May 2, 2003) which teaches a method of treating or preventing cardiovascular (coronary heart disease, atherosclerosis) disorder in an animal by administering a pharmaceutical or nutritional composition comprising yeast or bacteria (p. 4 lines 9-19, p. 5 lines 7-16, p. 7 lines 19-25 to p. 8 lines 1-3, p. 9 lines 6-7, p. 12 lines 15-19, p. 14 -16 and figure 5).

Also, search burden is not a requirement for restriction under PCT rules and only applies to applications filed under 35 U.S.C. 111. This application is filed under 35 USC 371 and thus the PCT criteria for restrictions which does not include search burden, applies.

As to the species election, the species requirement for animals and bacteria only applies to Group III and the species requirement for disease applies only to Group I. This demarcation was not clearly made on p. 3 of the restriction filed 6/3/08. Since Group I is elected the election of the disease atherosclerosis/coronary heart disease only applies and is acknowledged. This disease is known in the art as stated in the restriction requirement (Ross et al Nature 362:801-809, 1993) and thus the disease lacks unity with the other diseases. Furthermore, each of the diseases listed have different pathology or etiology or manifestations.

Thus for the reasons above the restriction requirement is still deemed proper and is therefore made FINAL.

Claims 24-43 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention and species, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 7/3/08.

Priority

Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

Information Disclosure Statement

The information disclosure statement (IDS) submitted on 7/16/08 has been considered by the examiner.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 22-23 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

The claims are broadly drawn to treatment or prevention of any disease comprising administering to any animal in need of such treatment any single cell material from any source.

Applicants' specification defines single cell protein material as a material comprising single cell microorganisms such as fungi, yeasts and bacteria. See page 9.

Thus, the claims are broadly drawn to using any pharmaceutical or nutritional composition comprising any fungi or any yeast or any bacteria to treat or prevent any disease in any animal. The scope of diseases is extremely broad and an alphabetic list of some diseases is set forth at Karolinska Institutet http://www.mic.ki.se/Diseases/alphalist.html retrieved Sept. 12, 2008. The diseases listed are extremely diverse from e.g. from different types of cancers to different genetic diseases to Yellow fever. All these disease have different underlying factors.

The specifications teaching is limited to lowering plasma cholesterol, lowering triacylglycerols in the liver, decreasing the activity of Acyl-coA:cholesterol acyltransferase (ACAT) and increasing mitochondrial beta-oxidation in obese Zucker rats comprising administering a pharmaceutical or nutritional composition comprising a particular single cell protein material combination from *Methylococcus capsulatus, Ralstonia sp, Brevibacillus agri and Aneurinibacillus sp*. See p. 17.

The specification is devoid of any guidance on how to treat or prevent all of the diseases listed using any single cell protein material. The instant application defines prevention as prevention of a given disease i.e. a compound of the present invention is administered prior to the onset of the condition … to prevent the risk or onset of a given disease (p. 9).

The specification lacks guidance as to which single cell protein material from which fungi or yeast or bacteria can prevent the onset or risk of all of the diseases listed in any subject or treat all the diseases listed.

Even though the instant specification teaches that single cell protein material combination from *Methylococcus capsulatus, Ralstonia sp, Brevibacillus agri and Aneurinibacillus sp* lowers plasma cholesterol, lowers triacylglycerols in the liver, decreases the activity of Acyl-coA:cholesterol acyltransferase (ACAT) and increases mitochondrial beta-oxidation in obese Zucker rats, the specification does not teach whether the animals had any disease (apart from the fact that they were obese) or whether the rats were at risk for any particular disease. For instance, the single cell protein material combination from *Methylococcus capsulatus, Ralstonia sp, Brevibacillus agri and Aneurinibacillus sp* lowered cholesterol in these animals but the specification does not teach whether these mice had abnormal levels of cholesterol and triacylglycerol in the first place. Therefore, it is not clear whether the administered composition was lowering cholesterol and triacylglycerol from high levels to normal levels. Thus, it cannot be determined whether the composition administered was treating any disease in these mice and it is therefore unpredictable that the effects of the administered composition in these mice correlates with treatment of any disease in any subject. Also, the specification does not correlate the effects of administering any single cell protein material to any animal model of disease with prevention of the onset of the disease in said animal model.

As to treatment or prevention of atherosclerosis/coronary heart disease, this disease is a systemic disease with many risk factors such as smoking, lipids and hypertension (Canto et al. JAMA August 20, 2003 Vol. 290 p. 947-949, Link et al. West J. Med. 2002. 174: 330-5 and Domanski et al NEJM 357; 15, p. 1543-1545). The art teaches that a comprehensive approach involving risk factor modification and pharmacological treatment is needed for effective prevention of cardiovascular disease (Canto et al p. 948 column 2 second to the last paragraph).

The instant specification does not teach that the composition administered to the obese Zucker rats treated or prevented atherosclerosis/coronary heart disease in said mice. The art teaches that the obese Zucker rat is an animal model of the metabolic syndrome; it carries mutation in the leptin receptor and exhibits genetic obesity, hyperlipidemia, insulin resistance and renal injury as recessive traits (Vaskonen et al J. Nutr. 132:231-237, 2002, p. 231 column 2 second full paragraph). Vaskonen et al (p. 231 column 2 second full paragraph) teaches that like other rodents and unlike humans, it normally has more HDL than LDL in circulation which would make it unsuitable for studies of atherosclerosis and that "human like" serum lipid profiles have to be induced in these mice by fat and cholesterol supplementation. Thus, the obese Zucker rat model used in the experiments in the specification is not a suitable model for atherosclerosis and the specification does not teach whether any "human like" conditions were induced in these mice to make them more suitable as models for studies on atherosclerosis, other cardiovascular diseases and risk factors for these diseases.

In conclusion, in view of the above considerations, undue experimentation would be required of the skilled artisan to treat or prevent any disease (including atherosclerosis/coronary heart disease) comprising administering to any animal in need of such treatment, a pharmaceutical or nutritional composition comprising any single cell protein material.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 22-23 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Pang et al. (WO 02/34273 A1 May 2, 2002).

The claims are drawn to a method of treating or preventing a disease comprising administering to an animal in need of such treatment, a pharmaceutical or nutritional composition comprising a single cell protein material (claim 22) wherein the disease is atherosclerosis/coronary heart disease (claim 23).

Applicants' specification defines single cell protein material as a material comprising single cell microorganisms such as fungi, yeasts and bacteria. See page 9.

Pang et al teaches a method of treating or preventing cardiovascular disorders such as coronary heart disease/atherosclerosis, atheroma, disorder to an animal a pharmaceutical or nutritional composition (e.g. yoghurt or soy) comprising yeast or bacteria (p. 4 lines 9-19, p. 5 lines 7-16, p. 7 lines 19-25 to p. 8 lines 1-3, p. 9 lines 6-7, p. 12 lines 15-19, p. 14 – p.16 and figure 5).

Claim 22 is rejected under 35 U.S.C. 102(b) as being clearly anticipated by Pedraglio et al (EP 0861905 A2 Sept. 2 19980

Claim 22 is drawn to a method of treating or preventing a disease comprising administering to an animal in need of such treatment, a pharmaceutical or nutritional composition comprising a single cell protein material (claim 22).

Applicants' specification defines single cell protein material as a material comprising single cell microorganisms such as fungi, yeasts and bacteria. See page 9.

Pedraglio et al teach a method of treating (therapeutic) or preventing (prophylactic) a gastrointestinal disorders (diarrhea, colitis, gastroenteritis etc) of human (animal) comprising administering to said human (animal) a pharmaceutical or nutritional composition (milk or yogurt) comprising *Lactobacilli* (single cell microorganism). See abstract, p. 5 lines 9-12, 32-58, p. 6 lines 1-14.

Status of Claims

Claims 22 and 23 are rejected. Claims 24-43are withdrawn. No claims allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to OLUWATOSIN OGUNBIYI whose telephone number is 571-272-9939. The examiner can normally be reached on M-F 8:30 am- 5 pm.

If attempts to reach the examiner by telephone are unsuccessful, either of the examiner's supervisors Shanon Foley (571-272-0898) or Robert Mondesi (571-272-0956) can be contacted. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Oluwatosin Ogunbiyi/

Examiner, Art Unit 1645

/Patricia A. Duffy/

Primary Examiner, Art Unit 1645